

The time period for reply, if any, is set in the attached communication.

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• .	PE	Application No.	Applicant(s)
	/ 10	09/476,689	STALKER, KENT C.B.
Office Action Sumr	mary SEP 07 2007	Examiner	Art Unit
	\2	hillip Gray	3767
The MAILING DATE of this Period for Reply	communication and	ars on the cover sheet wit	h the correspondence address
WHICHEVER IS LONGER, FROI  - Extensions of time may be available under the after SIX (6) MONTHS from the mailing date	M THE MAILING DA- ne provisions of 37 CFR 1.136 of this communication. maximum statutory period will nod for reply will, by statute, or ree months after the mailing d	TE OF THIS COMMUNIC  (a). In no event, however, may a re  apply and will expire SIX (6) MONT  ause the application to become ABA	Pply be timely filed  IFHS from the mailing date of this communication.  ANDONED (35 U.S.C. § 133).
Status			
1) Responsive to communicate	ion(s) filed on 28 Ma	rch 2007.	
2a) ☐ This action is <b>FINAL</b> .		action is non-final.	
\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \		·	ers, prosecution as to the merits is
closed in accordance with	the practice under Ex	parte Quayle, 1935 C.D	. 11, 453 O.G. 213.
Disposition of Claims			
4) Claim(s) <u>23-44</u> is/are pend	ing in the application		
4a) Of the above claim(s) _		n from consideration.	
5) Claim(s) is/are allow			•
6) Claim(s) 23-44 is/are rejec			
7) Claim(s) is/are objection   8) Claim(s) are subjection		election requirement	
Application Papers			·
9) The specification is objecte			Lotte Forming
10) The drawing(s) filed on			
Applicant may not request the	• •	• • •	(s) is objected to. See 37 CFR 1.121(d).
11) The oath or declaration is o	•		
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of	of a claim for foreign	priority under 35 H.S.C. 8	\$ 119(a)-(d) or (f)
a) All b) Some * c) N	<del>_</del>	priority under 55 5.5.5.	; 113(a) (a) 31 (i).
1. Certified copies of the		have been received.	
2. Certified copies of the	ne priority documents	have been received in A	application No
3. Copies of the certific	ed copies of the prior	ity documents have been	received in this National Stage
• •	International Bureau	· ·	
* See the attached detailed O	ffice action for a list of	of the certified copies not	received.
Attachment(s)		» 🗖	O(DTO 442)
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawir</li> </ol>		Paper No	Summary (PTO-413) (s)/Mail Date
3) Information Disclosure Statement(s) (F Paper No(s)/Mail Date	-	5)	Informal Patent Application (PTO-152)

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### **DETAILED ACTION**

This office action is in response to applicant's communication of 3/28/2007.

Currently amended claims 23-44 are pending and rejected below.

# Response to Arguments and Amendments

Applicant's arguments filed 3/28/2007 have been fully considered but they are not persuasive. Applicant argues that the addition of claim language "a directional member attached to the filtering member for directing body fluid and emboli into the filter member, the directional member being made from a pliable material having properties of blocking the passage of the fluid and the emboli and being expandable by the fluid flow in the body vessel to form a truncated conical shape when placed in an expanded position" distinguishes the applicants invention over the prior art of record, (Gilson).

It is examiners position that Gilson does disclose a directional member made of a pliable material and being expandable to form a truncated conical shape when in an expanded position, and further is fully capable of the functional operational limitations of directing body fluid into the filter member, blocking the passage and expandable by fluid flow. Examiner is of the position that the directional and filtering members (see rejection below) are made of a pliable material since the must navigate the body passage and are stored/carried in a flexible catheter structure. Further it is Examiners position that the directional and filtering members are in a "truncated conical shape", as shown in figures 40, 19C, and figures 14 and 15 (directional members 30 and filter element 31), Gilson shows that the directional member/filter element would have a "truncated conical

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shape" when in an expanded position. It is also examiners position that the Gilson directional member would block the passage of fluid and would be expanded by fluid flow (see figures 1, 8, 9, 10, and 18), and also described in paragraphs beginning at column 5 line 32.

Given this analysis of the claims and limitations, as described in the rejection below, the elements of Gilson are fully capable of satisfying the claimed limitations as currently written. The Gilson elements are fully capable of satisfying all structural, operational, functional, and spatial limitations as written in the claims. Therefore the rejections stand and are proper.

### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting

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directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 23-44 are rejected under 35 U.S.C. 102(e) as being anticipated by Gilson et al. (U.S. Patent Number 6,336,934). Gilson discloses an embolic protection device having a collapsible filter element (105) mounted on the end of a catheter (118) and optionally mounted on a tubular sleeve (104).

Concerning 23, 27, and 36, Gilson discloses an embolic filtering catheter apparatus containing a filtering portion (105), with directional member (50) being made from a pliable material, with no self-expanding properties, expandable by the fluid flow in the body vessel (see column 5, paragraphs at lines 30-40). When directional member is in elongated state, disposed against the vessel wall, the member directs blood, fluid and emboli into the relatively disposed filter member (see paragraphs at column 15, lines 24-41).

Concerning claims 23-24 and 29-30, the filtering member device is made from blood filtering material and braided/woven biocompatible material which is capable of blocking the passage of an emboli, and is expandable by the expansion of the directional member (see paragraph at column 15, lines 9-30). The expanded filtering directional device is a truncated conical shape (see column 14, lines 60-62, figures 37 and 39), that directs fluid into the filtering member (105).

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Concerning claims 25, 26, 31, 35, 37-39, and 44, Gilson discloses an embolic protection catheter device that contains an elongate tubing lumen with a slide-able shaft member adaptable to allow an interventional device to be advanced into position within a body vessel (as in figures 13-18). The filtering portion and member are disposed within the elongate tubing lumen in a compacted delivery position. These interventional devices may be advanced over the outer of inner surfaces of the elongate tubing lumen or inner sheath (as in figures 13-18 and 28-37). A shaft member (guide wire 101), contacting the interior of the filter member, is movable within the lumen for delivery and retrieval of the filtering means from the elongate shaft, is also disclosed in Gilson. Gilson further discloses a sheath/sleave (104) means for retracting the filtering means back into the lumen.

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Concerning claim 28, 32-34, and 40-43, the Gilson embolic filter device discloses a plurality of restraining wires (30) attached to the filter mesh (31) and directional member (34) from within the elongate lumen (35), which can retract the filter and directional member to the collapsed position and into a recovery sheath or sleave (104 or 32), via a location outside the body vessel (figures 11-15). These wires are held in a collapsed position during delivery of the filter member. The plurality of wires extend outward and may hold the filter open while the filter is deployed. (See paragraphs at column 10, line 55 through column 11, line 33)

# Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

**/**//*X* PAG PATRICIA BIANCO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

5/29/07

# Notice of References Cited Application/Control No. 09/476,689 Examiner Phillip Gray Applicant(s)/Patent Under Reexamination STALKER, KENT C.B. Art Unit 3767 Page 1 of 1

*		Document Number Country Code-Number-Kind Code	Date MM-YYYY	Name	Classification
*	Α	US-6,336,934	01-2002	Gilson et al.	606/200
	В	US-			
	С	US-			
	D	US-			
	Ε	US-			
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# FOREIGN PATENT DOCUMENTS

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### NON-PATENT DOCUMENTS

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\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).) Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.